



Natural and Medicinal Products Research
Life Sciences Division
American Institute For Biosocial and Medical Research
P.O. Box 1174 • Tacoma, WA 98401-1174 USA
(253) 922-0448; fx (253) 922-0479

May 12, 1999,

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Docket Management Branch (HFA-305)
Docket No. 98N-1038
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Subject: Food Irradiation, Docket No. 98N-1038

Dear FDA:

I am strongly opposed to reducing any labeling requirement of irradiated food as found in the 1986 Final Rules. I am also opposed to any future expiration date of the labeling requirement. This is a matter I personally reviewed while attending the meeting of the WHO Study Group on Health Promotion during its meetings in Copenhagen, Denmark, in 1986, as a voting member. The information provided to me at the time by WHO and others around the world convinced me that labeling of irradiated food was essential and prudent public health policy.

As consumers we want to know when foods have been processed by irradiation. In 1986, FDA determined in its Final Rule that irradiated foods should be labeled:

"...irradiation is a form of processing that can produce significant changes in certain characteristics of a food, such as the organoleptic (e.g., taste, smell, texture) or holding properties, in a manner that is not obvious to the consumer in the absence of labeling."

Irradiation today still causes these same changes. Hence, there is no scientific justification to reduce or minimize the requirement for the Radura symbol and the words "Treated with radiation" or "Treated by irradiation."

One of the reasons that food irradiation has failed to gain popularity is that consumers are concerned about the change in the structure of irradiated foods.

Not only does irradiation reduce nutrient value, it can create unique radiolytic by-products only as a result of such food processing. Although FDA has indicated that this experimental technology does not pose a threat to human health, many scientists and consumers remain skeptical and unconvinced of the agency's stance in this matter.

There is no "significant scientific agreement" that irradiated foods are safe for long term consumption. In contrast, many of the scientists who say irradiation is safe have known relationships with the nuclear industry or their governing bodies. In the mid-1980's in Canada, this matter was subjected to public hearings by its national Parliament. Hearings were held in each Province, and later in its chambers. After eight months of hearings and deliberations there was unanimous consensus by Canada's appointed Parliamentary committee to not allow food irradiation of foodstuffs intended for human consumption in Canada. Thereafter, the Canadian

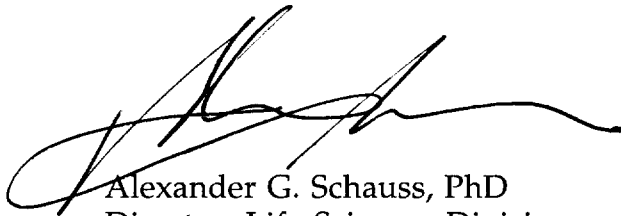
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Parliament debated the issue and agreed by consensus with this appraisal. Only pressure by Atomic Energy of Canada, fabricators of food irradiation equipment world-wide, was the Prime Minister persuaded to veto Parliament's decision in this matter. Time and time again, whether it be FDA or WHO, the issue has not been resolved by a fair evaluation of the scientific evidence, but on the basis of politics and economics. However, this matter is not about politics or economics but about public health. And this is the reason that FDA should make the right decision by insuring that foods irradiated are labeled as such, with clear language to that effect with the Radura logo.

As consumers we should have the right to know when our foods have been altered by experimental technologies that have not been proven to be safe.

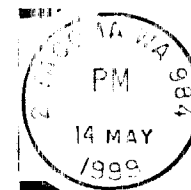
Sincerely,

A handwritten signature in black ink, appearing to read 'A. Schauss', with a long horizontal flourish extending to the right.

Alexander G. Schauss, PhD
Director, Life Sciences Division



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